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1. APPLICATION NUMBER	2. FILING DATE	3. ISSUE DATE	4. FIRST NAMED APPLICANT	5. ATTY. DOCKET NO.
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000151
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY NJ 07110

HM12/0926

EXAMINER
STOCKTON, L

ART UNIT PAPER NUMBER

1626 10

09/26/01
DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on September 17, 2001
 This action is FINAL.
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), September 17, 2001, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 7 and 21-24 are pending in the application.
Of the above, claim(s) 21 and 22 are withdrawn from consideration.
 Claim(s) is/are allowed.
 Claim(s) 7, 23 and 24 are rejected.
 Claim(s) is/are objected to.
 Claim(s) are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on is/are objected to by the Examiner.
 The proposed drawing correction, filed on is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) 09/508,714
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

09/475,943
U.S. GPO: 1998-404-07

DETAILED ACTION

Claims 7 and 21-24 are pending in the application.

Election/Restrictions

Applicants' election with traverse of Group II in Paper No. 9 is acknowledged. The traversal is on the ground(s) that: (1) it would not be a serious burden on the Examiner to search all of the claims at this time; (2) an election of species should not be required; and (3) it is improper for the Patent and Trademark Office to require a restriction within a single claim. Applicants cite *In re Weber et al.*, 198 USPQ 328 (CCPA 1978).

All of Applicants' arguments have been considered but have not been found persuasive. Section 121 provides the Commissioner of Patents and Trademarks with the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. In the instant application, the Examiner has

determined that several independent and distinct inventions are claimed in the application. As seen in the previous Office Action dated August 16, 2001 {Paper No. 8}, the inventions of Groups I and II are classified in two different areas. The proviso in claim 7 is also noted. Therefore, separate search considerations are involved which would impose an undue burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety. An election of species was required for examination only. The entire scope of elected Group II has been examined. Further, unlike in the instant application, the claims in In re Weber et al. were rejected under Section 121.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21 and 22 and subject matter not embraced by elected Group II is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/508,714, filed on April 11, 2000.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words.

It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The specification does not give any guidance as to the meaning of the phrase “and derivatives of said compounds”, which is found in claim 7 or how such derivatives of said compounds of formula (I) are made.

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. In order to practice the claimed invention, one skilled in the art would have to speculate what Applicants contemplated by the phrase "and derivatives of said compounds" and this would impose undue experimentation on the skilled art worker. Therefore, the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase “and derivatives of said compounds” in claim 7. The last compound in claim 23 and the first compound in claim 24 are misspelled.

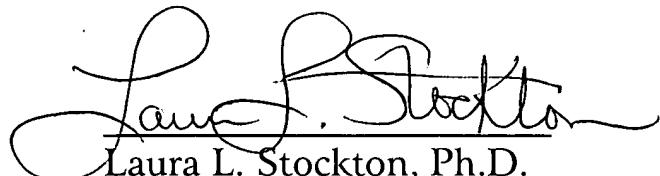
Allowable Subject Matter

The elected invention of Group II is free of the art of record. The closest prior art of record, PL 151315, fails to teach or suggest an unsaturated chain at the instant R¹ position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton, Ph.D. whose telephone number is (703) 308-1875.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or 305-3592.



Laura L. Stockton
Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

September 25, 2001